Minutes

Working Group on Aquaculture Drugs, Chemicals, and Biologics

February 28, 2011---New Orleans, Louisiana

Attendees

Jesse Trushenski (SIUC)
Thomas Bell (USFWS/AADAP)
Mark Gaikowski (USGS/UMESC)
Lester Khoo (AVMA/MSU)
Steve Sharon (WY Game and Fish/DAWG)
Bonnie Mulligan (SIUC)
Brian Gause (SIUC)
Mike Mason (IA DNR)
Jim Bowker (USFWS/AADAP)
Heidi Lewis (USFWS/AFTC)
Alan Johnson (IA DNR)
Jen Matysczak (FDA/CVM)
Jennifer Love (FDA/CVM)
Eric Landis (FDA/CVM)
Dave Straus (USDA/ARS)
Dave Erdahl (USFWS/AADAP)
Roz Schnick (Roz Schnick Consulting, LLC)
Malcom Pye (Fish Vet Group)
Pete Southgate (Fish Vet Group)
John Marshall (Fish Vet Group)
Dick Endris (Intervet/Schering-Plough)
Palma Jordan (Intervet/Schering-Plough)
Kaska Cox (Intervet/Schering-Plough)

Call to Order

JT called the meeting to order at 4:00 pm. She introduced the other WGADCB co-chairs in attendance—JB, LK, MG, SS, and Randy MacMillan (not in attendance).

Review and Accept Minutes

Minutes from the previous WGADCB meeting (August 4, 2010, Bozeman, MT) were published in the AFS Fish Culture Section and AADAP newsletters. JT asked for discussion relative to the meeting minutes. No discussion. Minutes accepted as published by unanimous consent.

Old Business

WGADCB response to FDA's request for public comments on Guidance Document #209 ("The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals") and the prevalence of unapproved animal drugs. JT provided a general overview of the WG members' comments. There has been some concern about the content of the comments, whether they reflect the position of the co-chairs (and their respective agencies), the WG as a whole, or simply the individuals submitting them. Despite these issues, the process has made people more aware of opportunities for public comment.

- JT asked for feedback on the usefulness of the public comment period announcements and talking points. Did the comments make some WG co-chairs/participants uncomfortable? Is providing "boiler-plate" comments within the role of the WG? Should the WG continue to produce such documents?
    - SS thought such documents were a good means of increasing public awareness
    - JB thought most people in the room currently understand issues and the Federal Register requests for comment, however, others outside the room may not understand the information or implications. For instance, hatchery biologists may not understand that the term "antimicrobial" as currently defined in the draft Guidance Document #209

includes substances such as formalin (and ostensibly would recommend the same approach to controlling the use of formalin as approaches used to control the use of antibiotics and all other antimicrobials), unless this specific point is made clear to them in the context of talking points provided by the WG. It is not the role of the WG to dictate comments to the public, but it should be the role of the WG to provide proper context so that individuals can understand the issues and provide their own substantive feedback.

- "Boilerplate" may be an inappropriate name for the comments that were prepared by WG members and distributed because it is not the role of the WG to dictate what people should say.
- JB indicated that there is considerable uncertainty surrounding the impact the comments have when reviewed by FDA. Questions often arise, such as whether comments should be more specific or general? Should the comment be general and information to help raise awareness to the general problem, or should they be specific to better help FDA fix a problem? It doesn't seem to be enough to say that "the process is broken and needs to be fixed" without providing solutions.
- JT acknowledged that for some issues, it is difficult for the co-chairs to come to a consensus in terms of comments or talking points. It is useful to have the talking points available for the public to use, but the WG co-chairs need to explore ways to distribute them without making co-chairs appear to support comments that they not fully agree with or putting them in a difficult situation with their employer, agency, etc.
- JM clarified that she herself does not see the comments, but that they go to a higher level within FDA. She also suggested that some issues may be dealt with at a lower level, outside of the context of public comment on Federal Register notices, if brought to her attention.
    - JT stated that the WG is trying to do both, but needs to figure out the best way to fix the process.

- Related to the topic of Federal Register comments is the issue of commenting on the Obama Administrations FY2012 budget. The budget contains items that may be of concern regarding funds available to support drug approval research. JT stated that WG participants need to be careful to distinguish between any comments they may make on the FY2012 budget (in the context of public comment periods) and lobbying, particularly given the fiscal nature of this issue.
    - MG summarized discussion from the Association of Fish and Wildlife Agencies (AFWA) Drug Approval Working Group (DAWG) meeting held prior to the WG meeting. The FY2012 budget includes a proposed decrease in U.S. Geological Survey (USGS) funds available to conduct aquaculture drug approval research. The proposed $700,000 decrease in funding may cause the Upper Midwest Environmental Sciences Center (UMESC) to lose their capacity to conduct any drug approval research. MG then recused himself from further discussion of the topic and any related WG action(s).
    - JT stressed to the WG that if USGS is not involved in aquaculture drug research, then it negatively impact progress relative to the overall drug approval because USGS is a major data generating partner. Avoiding the issue of lobbying, can the WG address this issue by putting together information emphasizing the importance of USGS's role in

aquaculture drug approvals? Can the WG request help from the American Fisheries Society in commenting on budgetary issues? The AFS does not lobby, but they have paid individuals who "educate" policymakers on fisheries-related issues and these individuals are currently reviewing the FY2012 budget and preparing their comments. Can the WG work with AFS so that AFS can provide feedback on the proposed budget cuts and educate/campaign for funding for various programs?

- SS—the DAWG will be providing comments to this effect through the appropriate channels within AFWA and yes, the WG should, too.
- JB asked if the U.S. Fish and Wildlife Service (USFWS) could provide comment on this issue since it is from one Department of Interior branch to another, or whether USFWS employees can comment on funding for another federal entity. Can the USFWS describe UMESC's contribution to the drug approval process and describe what would happen if they were no longer able to generate data?
- JT stated that she herself does not know where the line is when it comes to the WG's ability to provide guidance on budgetary issues, but the AFS Executive Direction and Policy Coordinator would know. The WG could ask them for help, if that is the direction the WG wants to go.
- JB stated that UMESC and AADAP conduct ~95% of the aquaculture drug research. If UMESC no longer has funds to conduct research in this area, some of the work that they conduct can be contracted to another party. Although drug approval progress would not shut down completely, it would be severely impacted.
- JT said she would speak with AFS Policy people and figure out what they need to proceed and how the WG can help.
- DS says as a representative of the American Veterinary Medical Association, a registered lobbying group, he is familiar with this process. He suggested that through the development of informational "fact sheets" about the contributions of USGS/UMESC to drug approval research, comments could be provided but would not cross the line into lobbying efforts. It was not clear who would develop these fact sheets.
- JT says that the AFS Executive Director has asked the unit leaders for input as to the FY2012 budget. JT acknowledges that WG co-chairs may have individual rules on what they can or cannot comment on, but that she can provide general information to AFS and have them carry the message instead of the WG. Regardless, the WG needs to figure out the best way to get our voice heard, collectively.

- DE asked if there is a fixed process for information dissemination, specifically, do all co-chairs see the "boilerplate/factsheets" and make comments before they are distributed?
  - JT said there has been a generalized pattern for preparing, reviewing, and distributing the comments. The first one was written and submitted by all the co-chairs. Subsequent comments were reviewed by the co-chairs, but not distributed or submitted with their signatures due to conflicts of interest or differences in personal opinion. All WG co-chairs see the comments and have an opportunity to make suggestions before they are distributed, but not everyone has to sign on before distribution to the WG participants, FCS membership, etc.
  - DE said it must be difficult for the WG to put out a comment if not all co-chairs are on board or haven't indicated if they are on board.

- JT—Yes, maybe the WG can look at how other groups form public comments and base our process off of theirs.
- JB—the U.S. Aquaculture Society (USAS) doesn't typically distribute information to their membership until the entire Board of Directors is in agreement, which can mean that members don't see the documents because it takes too long to get everyone to agree. Maybe the WG needs to think about how public comments are agreed upon before distribution. Form a consensus on how the co-chairs sign on or endorse the public comment.
- SS—All co-chairs should get to comment on the draft.
- JT—Perhaps a disclosure—"does not necessarily reflect the position of WG co-chairs or their employers"—can be added to the factsheets prior to distribution.

<u>"Guide to Using Drugs, Biologics, and other Chemicals in Aquaculture"</u>. JT reported that the Guide and accompanying treatment calculator are done and posted on the AFS FCS and AADAP websites. Positive feedback has been rolling in since these items were launched. JT thanked everyone involved in their revision/creation. Since the items are electronic-only, it makes it easy to update since each item is open to public comment on improvement.

- LK asked how often the Guide would be reviewed revised.
- General consensus was to initially revise the Guide every 3-6 months initially to work out the 'bugs', then revise as needed.

<u>AFS Policy Statement on the need for an immediate release sedative/anesthetic in fisheries.</u> JT updated the group that the draft policy statement is available on the AFS FCS website. A summary of the Policy Statement will be published in Fisheries magazine, and then AFS members have 60 days to comment. After the public comment period, the Policy Statement can be brought again before the AFS Governing Board and full membership for a vote to approve. JT does not see any major revisions to the statement on the horizon based on positive feedback from those who have reviewed it to-date.

- JB wants to get USAS on board with raising awareness for the need for an immediate-release sedative. AADAP is also getting comments on how people can help, and other comments regarding inclusion of other kinds of "generally regarded as safe" products in the Policy Statement.

<u>New Business</u>

<u>Involvement of the U.S. Aquaculture Society and other professional societies within the WG.</u>
JT and JB—General perception is that you have to be a FCS member to participate on the WG. Should the WG formally recognize a USAS board member as a co-chair of the WG?

- JB—when the WG formed in the aftermath of sunsetting the JSA Working Group, USAS was not formally recognized as a participant/contributor and this frustrated some USAS members. Including them formally in the WG may serve as an olive branch.
- LK—Yes, USAS should be included, and potentially other groups.
- DS—AVMA is already represented on the WG and so are many other groups
- JT—Point of clarification, AVMA wasn't specifically requested to serve as a contributor. Rather, Lester Khoo was asked to represent the veterinary community in general. In forming the WG,

general stakeholder groups—public data generating partners, private aquaculture, public aquaculture, the veterinary community, etc.—were targeted for representation, not individual professional organizations. Nonetheless, formally recognizing USAS in the context of appointing a representative co-chair may have some benefit. The WG is officially housed as an ad-hoc committee within the FCS, so the Section President can appoint co-chairs as his/her discretion.

- MG—Include other groups, including USAS, various producer groups, etc.
- JT—How many other groups/co-chairs? We don't want to end up with a committee so large it can't accomplish anything.
- JB—Avoid becoming top-heavy—offer a co-chair position to USAS first. If it works well, co-chairs from additional groups can be added as needed/desired.
- JT—Will contact incoming USAS President Michael Schwarz and ask him to identify a USAS Board member to serve within the WG.

White paper development. JT suggested that white papers can be a good way to harness the WG's collective expertise to address issues of concern. During the DAWG meeting, two topics were discussed that might benefit from the development of white papers to clarify the issues and facilitate decision-making: 1) considering pathogen/parasite species as groups rather than individual species in terms of drug approvals, and 2) articulating the differences between statistical significance, biological significance, and clinical relevance. Should the WG create white papers on these subjects? Is there value in this exercise?

- JB—For instance, if AADAP and UMESC are both working on one group of pathogens, we can work together to write a justification for lumping these pathogens together, but do we have all of the expertise need to fully address the issue? Can we tap expertise from others in the group?
    - MG—Yes, it would be easier to do a white paper within the WG than within USGS, for example. A wider net is cast for expertise, and less review is involved. The process would move forward faster.
    - SS—consolidation of all the expertise within the WG enables us to move faster to write the white paper.
- General discussion—Previous white papers have not been as effective as hoped, in part, because the papers might not have addressed all of the issues that FDA wanted to take in consideration. Alternatively, the white paper might address an issue for which FDA is simply not willing or able to use regulatory discretion. Communication between the WG participants and with the FDA will help the WG pick the most influential topics and improve the likelihood of success
    - ES—As-needed specific topics rather than generalized topics may provide the most impact
- JT—Should the DAWG prioritize issues or should this responsibility fall to the WG?
    - SS—only the public sector is represented in the DAWG, so more groups are represented in the WG.
    - JT—we will distribute a list and ask for issues to be prioritized for a white paper.
    - JB recommended addressing a relatively straight-forward issue first.

XXX—Action Item

    - JT tasked SS to put together a list to prioritize ideas and estimate value that can be generated from a white paper on this topic.
    - MG—engage FDA for their involvement and to see if the white paper topic would be accepted or considered.
- JM discussed potential topics:
    - Clinical significance is broad and may apply to certain drugs only (antiparasitics vs. antibiotics, etc.)
    - Lumping of *Gyrodactylus* species
    - Target animal safety data requirements
    - Labeling products—use patterns and issues with labeling requirements

Reengaging the MUMS Coalition—is it time to revisit MUMSA? JT provided background on AFS briefings for congressional staffers. They have been asked to provide a briefing on aquaculture drug access/use/importance in the public and private sector and to identify ways to improve the drug approval process to allow for greater access while still ensuring public safety and animal health and well-being. JB was asked to provide further context for how this planning process led to a discussion of whether it was time to revisit the Minor Use-Minor Species Act and other legislation related to animal drug approvals.

- JB said that Randy MacMillan pointed out that rewriting MUMSA would take time, money, and people (even perhaps hiring a lobbyist). The focus then turned to what could be accomplished through less sweeping changes, i.e., small revisions to the existing statutes, regulatory change, etc. What should we recommend, how do we do it, and who on Capitol Hill would be best to speak with? The briefing should provide information on things Congress can actually help with. We should discuss doable goals, nothing too broad. We also need to be specific and clearly articulate what it is that we want help with.
- JT—the WG could provide feedback and constructive criticism for this process.
- DS indicated that key people have been invited to a meeting to be held on March 1, 2011 to discuss immerging ideas to refine MUMSA, perhaps through the context of a congressional briefing.

AVMA presentation to Roz Schnick LK presented an award to Roz Schnick recognizing her leadership and involvement in the drug approval process over the years.

Meeting Adjourned

XXX—Action Item